GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

LOURDES A. LEON GUERRERO
GOVERNOR, MAGA'HÅGA'

JOSHUA F. TENORIO
LT. GOVERNOR, SIGUNDO MAGA'LÅHI

ARTHUR U. SAN AGUSTIN, MHR
DIRECTOR

LAURENT SF DUENAS, MPH, BSN
DEPUTY DIRECTOR

TERRY G. AGUON
DEPUTY DIRECTOR

Standing Order for Administering COVID-19 Vaccines Addendum

Update as of May 23, 2022

This addendum includes the following:

1. New guidance for use of a Pfizer-BioNTech COVID-19 Vaccine booster dose in children ages 5–11 years
2. Updated guidance that the following people **should** receive a second COVID-19 booster dose:
    a. People ages 12 years and older who are moderately or severely immunocompromised
    b. People ages 50 years and older
3. Updated guidance for people who are moderately or severely immunocompromised and are treated with B-cell-depleting therapies
4. Clarification of COVID-19 vaccination guidance for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A)
5. Updated guidance for primary series vaccination after SARS-CoV-2 infection

Updated Guidance for children ages 5 through 11 receiving the Pfizer-BioNTech Vaccination Booster Dose

CDC now recommends that children ages 5 through 11 years should receive a booster dose 5 months after their initial Pfizer-BioNTech vaccination series.

Guidance for COVID-19 Vaccination for people ages 12 years and older who are Moderately or Severely immunocompromised

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. Because the immune response following COVID-19 vaccination may differ in moderately or severely immunocompromised people, specific guidance for this population is provided. **Use of mRNA vaccines is preferred**.

Booster doses for people who are Moderately or Severely immunocompromised

All people ages 5 years and older and who are moderately or severely immunocompromised should receive at least 1 booster dose. An mRNA vaccine is preferred for the first booster dose. Any age-appropriate mRNA vaccine can be used for the booster dose(s): it can be the same mRNA vaccine as the primary series (homologous booster) or a different mRNA vaccine (heterologous booster). Janssen should only be used in limited situations and cannot be used as a second booster dose.

mRNA COVID-19 vaccine primary series:

- People ages 5-11 years: Should receive 1 booster dose at least 3 months after the third primary dose, for a total of 4 doses.
- People ages 12 years and older: Should receive 2 booster doses. The first should be administered at least 3 months after completion of the primary series and the second at least 4 months after the first booster dose, for a total of 5 doses.

Special situation: For people who inadvertently received the booster dose before their third primary dose, regardless of type of vaccine received as the booster dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 µg [0.5 mL, red cap vial]) as the fourth dose (third primary) at least 3 months after the third dose.

Janssen COVID-19 primary series:

People ages 18 years and older should receive 2 booster doses. The first should be administered at least 2 months after the second (additional) dose and the second at least 4 months after the first booster dose, for a total of 4 doses.

Special situation: Many recipients of Janssen COVID-19 Vaccine may have received a booster dose (Pfizer-BioNTech, Moderna [50 µg], or Janssen vaccine), without having had the second (additional) mRNA vaccine dose. In this situation, regardless of type and timing of vaccine received as the second dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 µg [0.5 mL, red cap vial]) as the third (additional) dose at least 2 months after dose 2.

A second booster dose using an mRNA vaccine could benefit people who are moderately or severely immunocompromised, as they are at increased risk for severe COVID-19. These people may choose to receive a second booster dose using an mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose, **for a total of 4 doses**.

Table 1: COVID-19 vaccination schedule for people who are moderately or severely immunocompromised*

Primary vaccination	Age group	Number of primary vaccine doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	5 years and older	3	1 - 2	3 weeks	At least 4 weeks	At least 3 months
Moderna	18 years and older	3	1	4 weeks	At least 4 weeks	At least 3 months
Janssen	18 years and older	1 Janssen, followed by 1 mRNA	2	4 weeks	At least 2 months	NA

Abbreviation: NA = not applicable

*Number of booster doses for people who are moderately or severely immunocompromised:

- All people ages 5 years and older: **Should** receive 1 booster dose of an age-appropriate COVID-19 vaccine; an mRNA COVID-19 vaccine is preferred.
- People ages 12 years and older: **Should** receive a second booster dose using an age-appropriate mRNA COVID-19 vaccine at least 4 months after the first booster dose.

Moderate and Severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Self-attestation of immunocompromised status:

People can self-attest to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

Booster doses for people who are *not* moderately or severely immunocompromised

All people ages 5 years and older should receive at least 1 booster dose. An mRNA vaccine is preferred for the first booster dose. Any age-appropriate mRNA vaccine can be used for the booster dose(s): it can be the same mRNA vaccine as the primary series (homologous booster) or a different mRNA vaccine (heterologous booster). Janssen should only be used in limited situations and cannot be used as a second booster dose.

Interval between primary series and booster doses

***First booster dose**:* The recommended interval is based on the product received for the primary series. In most people, the interval is:

- At least 5 months after an mRNA 2-dose primary series or
- At least 2 months after a Janssen single-dose primary series

***Second booster dose**:* The recommended interval between the first booster dose and the second booster is at least 4 months, regardless of primary series or first booster dose product.

Table 2. COVID-19 vaccination schedule for people who are ***not*** moderately or severely immunocompromised*

Primary series vaccine manufacturer	Age group	Number of doses in primary series	Number of booster doses†	Interval between 1st and 2nd primary doses†	Interval between primary series and booster doses
Pfizer-BioNTech	5 years and older	2	1 - 2	3-8 weeks	At least 5 months
Moderna	18 years and older	2	1 - 2	4-8 weeks	At least 5 months
Janssen	18 years and older	1	1 - 2	NA	At least 2 months

Abbreviation: NA = not applicable

*For the vaccination schedule for people who are moderately or severely immunocompromised, see Table 1
†Number of booster doses for people who are not moderately or severely immunocompromised are as follows:

- All people ages 5 years and older: Should receive 1 booster dose of an age-appropriate COVID-19 vaccine; an mRNA vaccine is preferred.

- People ages 18-49 years: Those who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the Janssen booster dose.
- People ages 50 years and older: Should receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster

‡An 8-week interval may be optimal for some people ages 5 years and older, especially for males ages 12–39 years. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

Considerations for timing of Covid-19 vaccination in relation to immunosuppressive therapies

Administration of COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies. Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. For patients who receive B-cell-depleting therapies on a continuing basis, COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy.

Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine but before administration of a subsequent dose of COVID-19 vaccine

Development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided.

Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine. If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until at least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise the use of Janssen COVID-19 Vaccine be considered instead of mRNA COVID-19 vaccines. These people should be aware of the risk of TTS. Considerations for subsequent vaccination may include:

- The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Level of COVID-19 community transmission and personal risk of infection

- Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information.

History of myocarditis or pericarditis prior to COVID-19 vaccination

People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team.

People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)

MIS-C is a rare but severe condition in children and adolescents infected with SARS-CoV-2. MIS-A is even rarer and less well characterized. Both include a dysregulated immune response to SARS-CoV-2 infection. The risk of recurrence of a dysregulated immune response following reinfection with SARS-CoV-2, or an MIS-like illness following COVID-19 vaccination is unknown; however, it is unknown if this correlates with protection against reinfection and for how long the protection might last.

There are limited data on the safety of COVID-19 vaccines in people who have had MIS-C or MIS-A from SARS-CoV-2 infection and who have not yet received COVID-19 vaccine. A conversation between the patient, their guardian(s), and their clinical team or a specialist (e.g., specialist in infectious diseases, rheumatology, or cardiology) is strongly encouraged to assist with decisions about the use of COVID-19 vaccines in such situations.

Considerations for starting the COVID-19 vaccine series in people with MIS-C or MIS-A

Experts consider the benefits of COVID-19 vaccination for children and adolescents (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for people who meet all of the following criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been ≥90 days since their diagnosis of MIS-C;
3. They are in an area where the COVID-19 community level is high or otherwise have an increased risk for SARS-CoV-2 exposure and transmission; and
4. Onset of MIS-C occurred before any COVID-19 vaccination (For people diagnosed with MIS-C or MIS-A after COVID-19 vaccination see the relevant section below).

COVID-19 vaccination may also be considered for people who have not yet received COVID-19 vaccine and either have a history of MIS-C from SARS-CoV-2 infection and do not meet all the above criteria or have a history of MIS-A from SARS-CoV-2. Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors when considering individual benefits and risks include:

1. An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)
2. Timing of immunomodulatory therapies (ACIP's general best practice guidelines for immunization can be consulted for more information.

People diagnosed with MIS-C or MIS-A after COVID-19 vaccination

In the rare instance a person develops MIS-C, MIS-A, or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, and/or cardiology should be considered. Assessment should include testing for current or prior SARS-CoV-2 infection. Obtaining a serum sample before any Intravenous immune globulin (IVIG) is administered is highly recommended so that the sample can be tested for SARS-CoV-2 anti-nucleocapsid antibody, which typically requires a reference laboratory. A positive anti-nucleocapsid antibody test result indicates prior SARS-CoV-2 infection. (To test for current SARS-CoV-2 infection, a molecular diagnostic or antigen test should be used). Anti-spike protein antibody testing cannot be used to determine SARS-CoV-2 infection status in a vaccinated person, because a positive test result can be induced by either COVID-19 vaccination or SARS-CoV-2 infection.

A discussion between the patient, their guardian(s), and their clinical team is strongly encouraged to assist with decisions about subsequent doses of COVID-19 vaccine for people who have onset of MIS-C or MIS-A after receiving a vaccine dose but who have not yet completed all recommended doses.

<u>Additional considerations for MIS-C may include:</u>

- For people who have onset of MIS-C 90 days or more after the date of their most recent COVID-19 vaccine dose, administration of subsequent COVID-19 vaccine dose(s) should be considered if the first 3 criteria in the section above ("Considerations for starting the COVID-19 vaccine series in people with MIS-C or MIS-A") are also met.
- For people who have onset of MIS-C fewer than 90 days after the date of their most recent COVID-19 vaccine dose, subsequent COVID-19 vaccine dose(s) should be deferred at this time until additional data are available.
- However, on a case-by-case basis, a provider and the family may choose to provide subsequent dose(s) if the first 3 criteria in the section above ("Considerations for starting the COVID-19 vaccine series in people with MIS-C or MIS-A") are met, and there is strong evidence that the MIS-C was a complication of a recent SARS-CoV-2 infection.

Vaccination and SARS-CoV-2 testing

Antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result.

For complicated situations, not addressed by the guidance above, healthcare and public health professionals may consider requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project. An illness consistent with MIS-C or MIS-A after receivingCOVID-19 vaccine should be reported to VAERS.

For more information refer to CDC Interim Clinical Consideration for use of COVID-19 Vaccines at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. See media statement.

This policy and procedure shall remain in effect for all patients of DPHSS until rescinded in writing by the Department.

Robert Leon Guerrero MD

05/22/2022

ROBERT LEON GUERRERO, MD **DATE**
Immunization Advisor
Interim Chief Medical Officer